

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



OPP OFFICIAL REVIEW OF  
HEALTH EFFECTS OF PESTICIDES  
SCIENTIFIC DATA REVIEWS  
EPA SERIES 361

OFFICE OF CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM**

**Date:** October 18, 2011

**SUBJECT:** Ethylene Thiourea (ETU). Joint Review by EPA and PMRA of Kinetic Justification for Dose Adjustments for a Proposed Extended One-Generation Reproduction Study

**PC Code:** 600016

**Decision No.:** N/A

**Petition No.:** N/A

**Risk Assessment Type:** N/A

**TXR No.:** 0056110

**MRID No.:** 48597301

**DP Barcode:** D394376

**Registration No.:** N/A

**Regulatory Action:** N/A

**Case No.:** N/A

**CAS No.:** 9006-42-2

**40 CFR:** N/A

Ver. Apr. 2010

**FROM:** Kit Farwell, D.V.M.  
Risk Assessment Branch VII  
Health Effects Division (7509P)  
Office of Pesticide Programs

*Kit Farwell*

**THROUGH:** Michael Metzger, Branch Chief  
Risk Assessment Branch VII  
Health Effects Division (7509P)  
Office of Pesticide Programs

*Michael Metzger*

**TO:** Kaitlin Keller  
Pesticide Re-Evaluation Division  
Risk Management and Implementation Branch 3 (7508P)  
Office of Pesticide Programs

**Action requested:** EPA toxicologists Kit Farwell and Elizabeth Mendez and Health Canada PMRA toxicologist, Lauri Stachiw, discussed a document submitted by the Dow Chemical Company, "Exposure to ETU During Different Life Stages: Kinetic Considerations" (MRID 48597301). The document reported toxicokinetic data to justify adjusting dietary concentrations in a planned extended one-generation reproduction study with ETU.

*Rec'd RRC  
10/20/11  
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Dow Chemical Company had previously submitted protocols for an extended one-generation study which were evaluated by EPA and PMRA (memos: D386090, 1/25/11 and D388513, 5/3/11; email: to Christina Scheltema, 6/9/11).

**Conclusions:** EPA and PMRA agree with Dow that the toxicokinetic data for ETU support reducing dietary concentrations to one-half normal for lactation days 14-21 and postnatal days 21-35.

The 0.2 and 2.0 mg/kg/day doses used by Dow for the low- and mid-dose groups are too low. EPA and PMRA recommend doses of 1.0, 5, and 10 mg/kg/day so that a dose-response effect for thyroid toxicity can be demonstrated.

The decision to allow adjusting the dietary concentrations in this study was reached after consideration of the toxicokinetic data and numerous communications with Dow about this study. If dose adjustments are desired for future studies, the registrant should again communicate with the Agencies before beginning the study.



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# R195285

**Chemical Name:** Ethylenethiourea

**PC Code:** 600016

**HED File Code:** 13000 Tox Reviews

**Memo Date:** 10/18/2011

**File ID:** 00000000

**Accession #:** 000-00-0137

**HED Records Reference Center**  
10/20/2011